Heidelberg Edge Perimeter

Installation and System Configuration

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HEIDELBERG ENGINEERING

CE 0482

The manufacturer hereby declares that this product conforms to the requirements of Directive 93/42/EEC of the Council of the European Community dated 14 June 1993 regarding medical products (MDD 93/42/EEC).

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Table of Contents

1 GENERAL INFORMATION 4

1.1 THE MEDICAL DEVICE HEP 4

1.2 THE HEP SYSTEM 5

1.3 REGULATORY STANDARDS 5

1.4 THIRD PARTY HARDWARE AND SOFTWARE 5

1.5 SAFETY INFORMATION, CAUTIONS AND WARNINGS 7

1.6 MAINTENANCE 8

2 HARDWARE INSTALLATION 9

2.1 UNPACKING THE HEP 9

2.2 INSTALLING THE EXTERNAL TFT MONITOR 11

2.3 SETTING UP CABLE CONNECTIONS 12

2.4 POWER-UP SEQUENCE: 13

2.5 TRANSPORTATION INSTRUCTIONS: 13

3 OPERATING SOFTWARE INSTALLATION 14

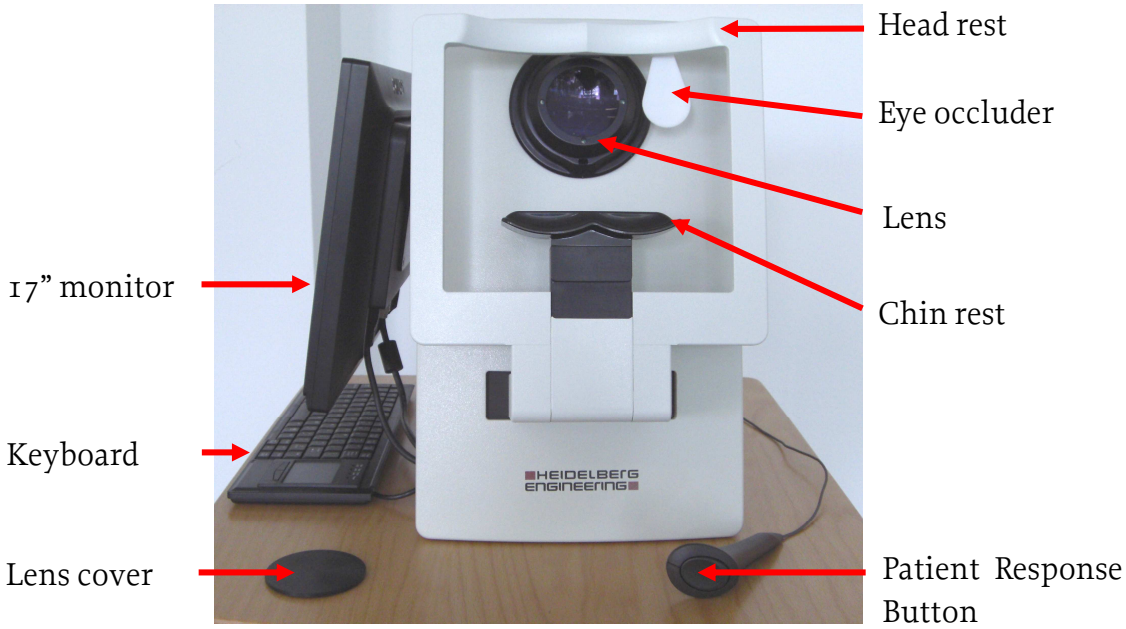
3.1 OPERATING SOFTWARE - UPDATE 14

4 INSTALLATION INSTRUCTIONS FOR SHARING DATABASES BETWEEN HRT AND HEP 17

1 General Information

1.1 The Medical Device HEP

The Heidelberg Edge Perimeter (HEP) is designed to provide comprehensive functional testing of the visual system. It employs traditional visual field measurement techniques such as Standard Automated Perimetry (SAP), along with a unique new visual function-specific stimulus called Flicker-Defined Form (FDF). This enables full scope perimetric evaluation of patients with retinal, optic nerve and neurological defects. The FDF stimulus is specifically designed for the early detection of glaucomatous visual field changes.
Standard Automated Perimetry (SAP) may be considered more suitable for the detection and monitoring of neurological defects, moderate to severe glaucoma and other conditions associated with extensive and deep visual field loss, such as ischemic optic neuropathy.



1.2 The HEP System

The HEP can work alone as a stand-alone perimeter or in combination with the Heidelberg Retina Tomograph (Model HRT 2 or 3 with software version 3.1 or higher) for a comprehensive glaucoma analysis of structure and function.

The HEP alone and together with other connected devices constitutes a medical electrical system ("ME system") according to IEC 60601-1-1. This system must meet specific safety criteria as detailed in the standard and in this document. *Note that every connected device will become part of the ME-System even if the only connection is the power supply cord leading to a shared multiple socket outlet.*

WARNING The ME system may only be assembled by qualified personnel with training and knowledge in electrical safety, heeding all instructions and safety warnings contained in this document. It is especially important that all users that de-install and reinstall the system (for example in a mobile use scheme) are trained to do this in a safe way.

For setting up a safe system it is essential to read and understand the below section *Safety Information*.

1.3 Regulatory Standards

The HEP complies with the international IEC 60601 standard series concerning medical electrical equipment. These standards are published by the International Electrotechnical Commission and are the base of most national and regional standards for medical electrical equipment worldwide.

Some local standards contain deviations from the IEC versions. These standards include UL 60601-1 (USA), CAN/CSA C22.2 No. 601.1 (Canada), JIS T 0601-1 (Japan), AS 3200.1.0. (Australia) and others. *Wherever IEC 60601-Standards are mentioned inside this document, the according regulations of respective local standards are also implied.*

NOTICE Even though the HEP already conforms to most local standards for medical devices in its default configuration, actual conformance can only be ensured by buying it from an authorized local Heidelberg Engineering distributor.

1.4 Third Party Hardware and Software

1.4.1 Isolation Transformer

HEP device, TFT monitor and all mains supplied accessories need to be supplied through an isolation transformer:

- Noratel Germany AG, model: IMEDi 300WR (300 VA) or
- DeMeTec, Germany, type IPS (330 VA)

Make sure that the total power consumption does not exceed the specified electrical power output for each individual isolation transformer as indicated above.

1.4.2 Printers

The HEP device can be operated with any standard inkjet printer.

To ensure safe operation, please note that they must have CE and/or FCC approval.

1.4.3 External Devices

The HEP device can be operated with the following external devices:

- USB hub
- USB storage device
- External DVD-RAM drive

To ensure safe operation, please note:

- USB hub and storage device must have CE and/or FCC approval.
- USB hub and storage device must be powered from USB port only.

1.4.4 Anti-virus Software

Use the HEP device exclusively with AVG antivirus software. Other antivirus software may interfere with FDF stimulus presentation.

When installing the antivirus software per manufacturer's recommendation, configure it so it does not scan automatically. Otherwise it may interrupt the operation of the device.

1.5 Safety Information, Cautions and Warnings

This section contains important safety information. Please read it carefully!

1.5.1 General Safety Information

IMPORTANT Before you start working with the instrument, make sure that you know the correct procedures for turning the instrument on and off (see HEP Operation Instructions).

IMPORTANT Carefully read the instructions for use before operating the device. Misuse of the device may lead to hazards for the patient or the operator or can lead to wrong diagnostic results. Use outside the "intended use" scope may also lead to instrument damage.

The instrument must not be used if there is a mechanical, electrical, or optical defect. Modifications or additions lead to loss of conformity. Heidelberg Engineering does not take responsibility for modified HEP devices.

Any repair, especially of the instrument's electric and electronic systems, and any service work on the instrument components, must only be carried out by Heidelberg Engineering or an authorized distributor.

1.5.2 Warnings and Cautions

WARNING To avoid the risk of electric shock, the system must be installed in accordance to IEC 60601-1-1 or the corresponding local standard particularly with regard to the electrical leakage currents. Every modification to the system requires a new evaluation of the requirements of said standard.

WARNING If your system configuration includes a multiple socket outlet, do not place it on the floor as this entails the risk of liquid ingress or accidental mechanical damage.

WARNING Do not connect an additional multiple socket outlet or an extension cable to the system. This would lead to increased protective earth impedance and therefore to an increased risk of electric shock.

WARNING Do not connect additional devices to the system that are not part of the system or not specified as compatible to the system.

WARNING Do not use multiple socket outlets that are part of the HEP system for other devices that are not part of the system (e.g. office equipment, domestic appliances). This would lead to increased electrical leakage currents and therefore to an increased risk of electric shock for both patient and operator.

WARNING Devices intended to be used together with a separating transformer (or '*isolating transformer*') may not be used without that transformer. A bypass of the separating transformer may lead to excessive electrical leakage currents and therefore to an increased risk of electric shock.

WARNING Do not touch the patient and parts inside access covers or contacts of connectors of nonmedical devices simultaneously.

WARNING Carry out all cleaning, adjustment, sterilization and disinfection procedures as specified in the enclosed instructions for use of the particular system components.

Refraining from that may lead to infections or to bad measurement results that again may lead to a false diagnosis.

If a multiple socket outlet is used as part of the system, it must conform to IEC 60601-1-1, in particular it must only allow connection of power cords by using a tool.

All parts of the system can be used inside the patient environment if the requirements defined in this document and in the according standards are met.

For instructions for cleaning and permissible environmental conditions, see the enclosed instructions for use of the particular system component.

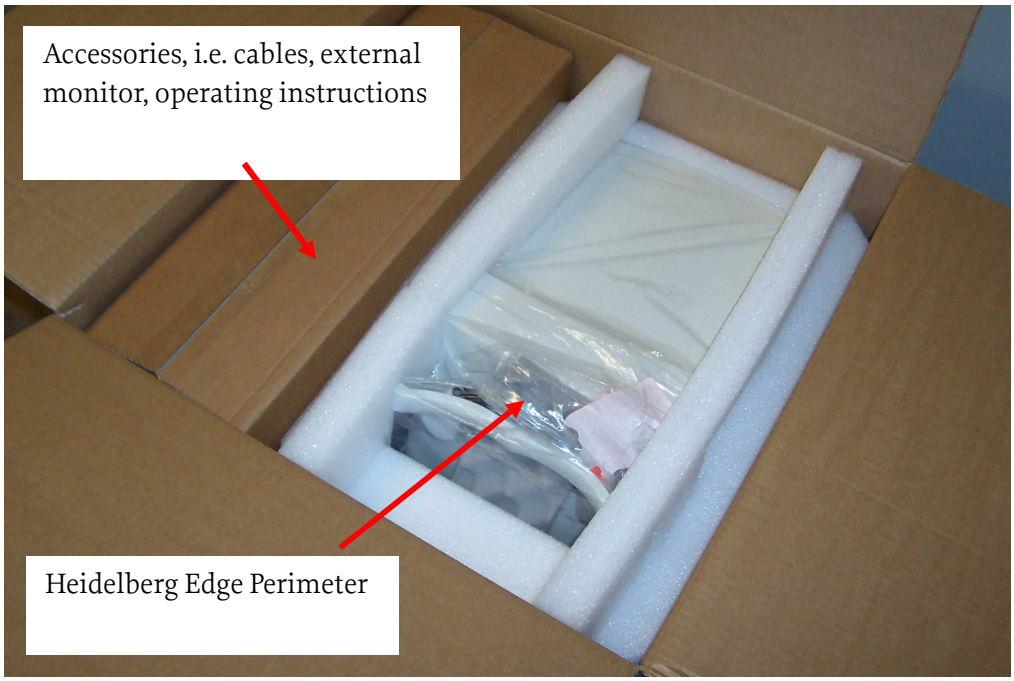
1.6 Maintenance

For details on cleaning and maintenance, please refer to the HEP Operation Instructions.

2 Hardware Installation

2.1 Unpacking the HEP

Carefully open the HEP box (view from the top):



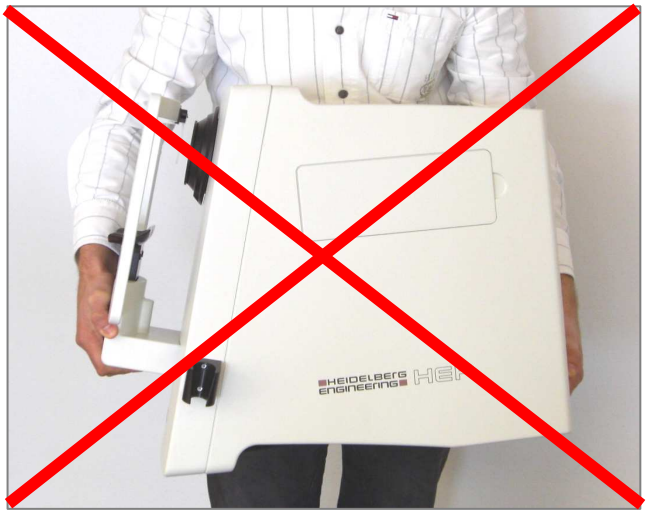
Remove the box on the left with the HEP accessories (monitor, cables).

Remove the top foam cover:

Take the whole HEP system out of the box and place it on a plane surface.

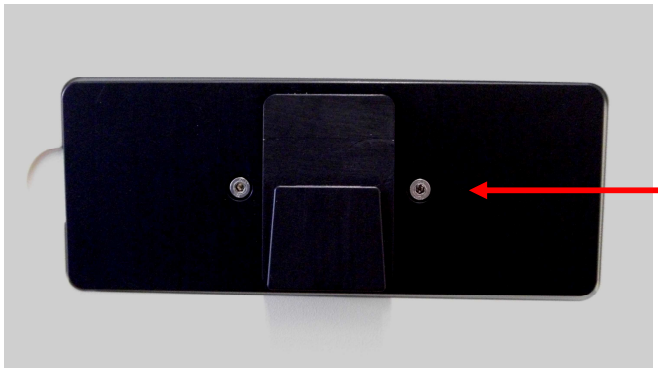
Make sure you always pick up the HEP placing your hands around the bottom of the instrument.

Note: Be careful to never lift the HEP at its chin rest (left image) nor at its head rest (right image).



2.2 Installing the External TFT Monitor

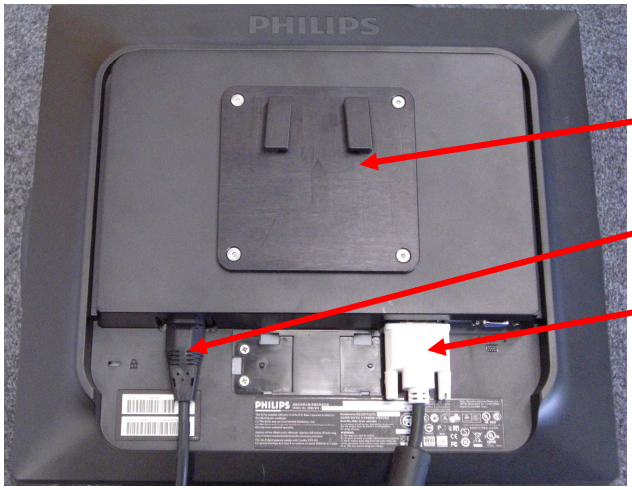
The external TFT Monitor is part of the HEP accessories. The monitor can be mounted on either side of the instrument, depending on the practice's or clinic's facilities.



Monitor mount with hexagon sockets

After slightly unscrewing two hexagon sockets, the monitor mount position may be changed. After adjustment, refasten the hexagon sockets again.

The mount counterpart can be found at the back of the monitor. The monitor can easily be hooked up at the HEP.



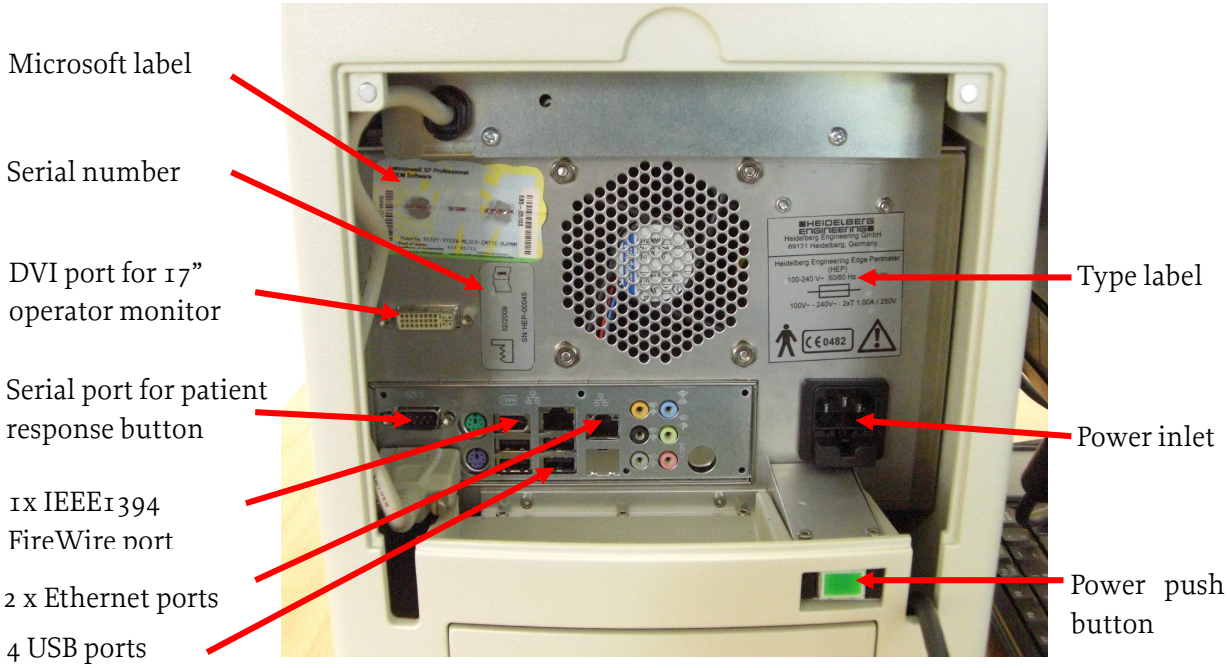
2.2.1 Isolating Transformer

Connect the low heat devices i.e. HEP system, the height adjustable table and printer (if applicable) to the isolating transformer using the cables for low heat devices.

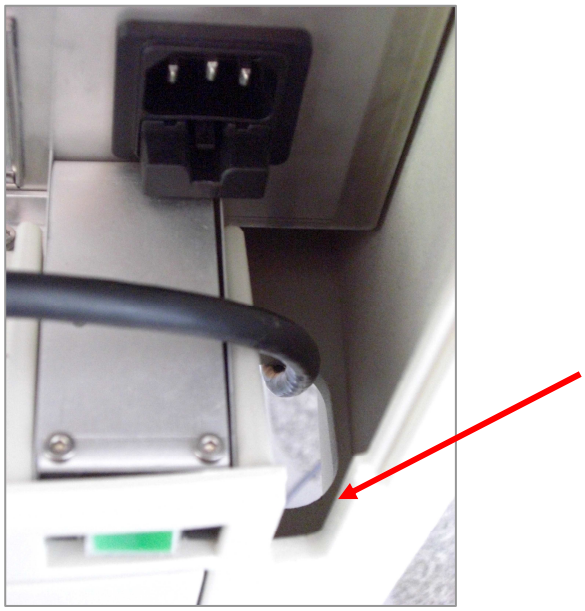
Connect the power cable to the isolating transformer. Do not connect the power cable to the mains yet.

2.3 Setting up Cable Connections

Open the cover on the backside of the HEP instrument.



Connect the DVI monitor cable, the patient response button, the keyboard, the mouse if not using a touchpad on the keyboard and the main power cable.
Attach the power cord to the power socket.



The bottom plate of the HEP contains two holes. The following cables can be guided through these holes from underneath the HEP: keyboard, mouse, patient response button, DVI monitor cable.
Note: Make sure the instrument is not accidently placed on a cable.

2.4 Power-up Sequence:

1) Turn on the external 17" monitor.

2) Turn on the HEP by pressing the power push button for several seconds until you hear the computer starting up.

Note: The external monitor must always be turned on before the HEP. If the HEP is turned on while the external 17" monitor is off, the Windows operating system will automatically select the internal CRT monitor as primary display and not extend the desktop to the external monitor. In such a case, please disconnect and then reconnect the power cord at the back of the HEP and follow the proper power-up sequence described above.

After software installation (see below), attach the USB software protector (dongle) to the back of the HEP instrument and close the instrument back with the cover.

2.5 Transportation Instructions:

When transporting the HEP the instrument must be packaged in the original packaging material. To pack up the HEP, repeat the steps 2.1 to 2.4 in reverse order.

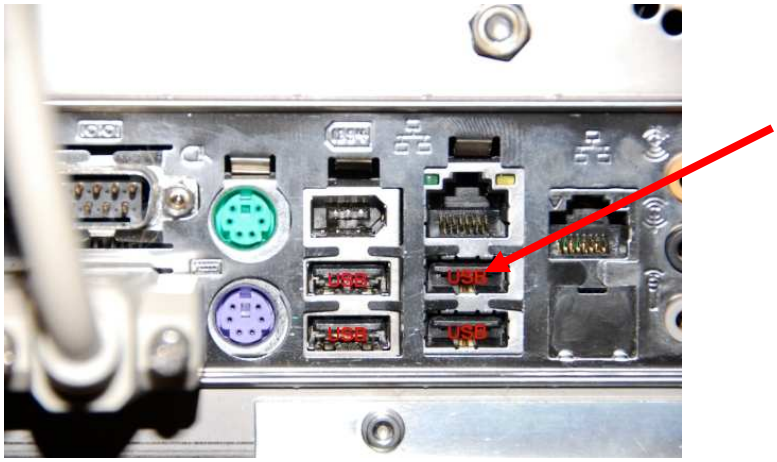
3 Operating Software Installation

To install the software for the Heidelberg Edge Perimeter, insert the USB key delivered with the instrument into the USB-drive at the back of the HEP and wait for the automatic startup of the installation program or manually run the “setup.exe” program from the root directory of the USB key.

Note: To avoid virus infection of the HEP, the USB key delivered with the HEP must not be inserted in any other instrument or computer but the HEP.

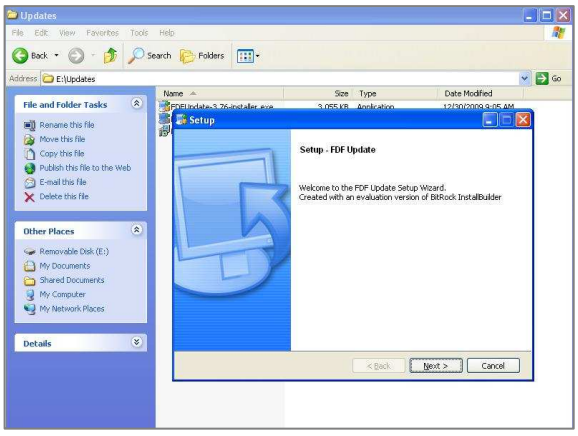
3.1 Operating Software - Update

In case of a software update (i.e. an older version of the Heidelberg Edge Perimeter software is already installed on the system), plug a virus-free USB memory stick containing the update software into one of the four USB ports in the back of the HEP instrument. Note that one port will already be occupied by the USB keyboard.

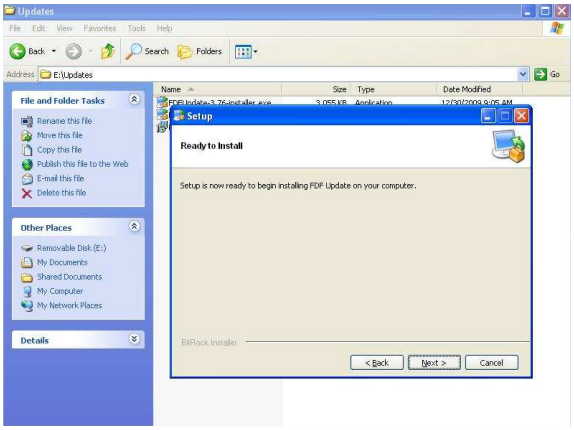


If no window appears showing the USB memory stick’s contents automatically, open it by double clicking the ***My Computer*** icon located in the top left corner of the Desktop. Then double click the ***Removable Disk (D:)*** icon near the bottom of the window.

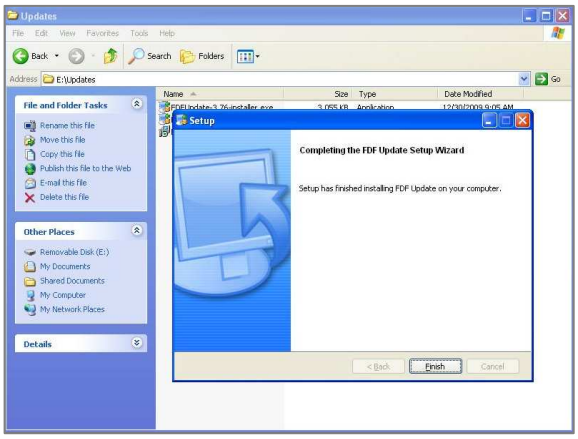
Double click the installer program to start the installation process. When the ***FDF Update*** window appears, click the ***Next*** button.



When the ***Ready to Install*** dialog appears, click the ***Next*** button.



When the installer completes the update procedure, click the ***Finish*** button, and remove the USB memory device.

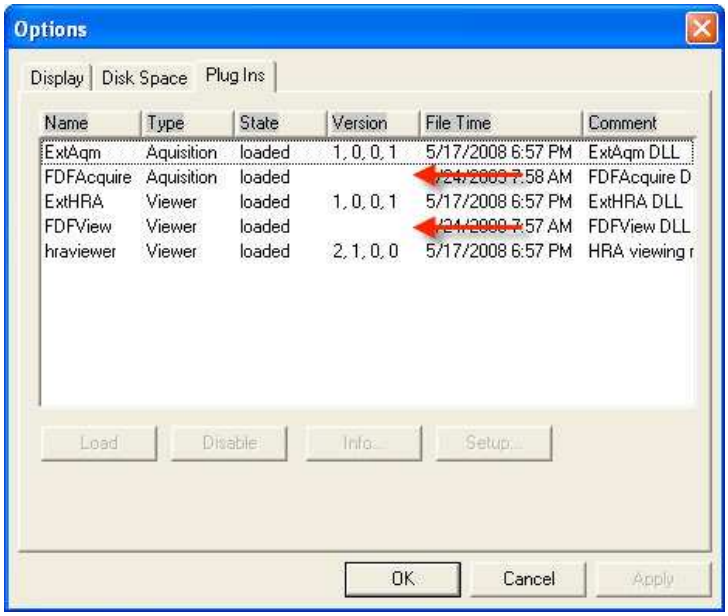


3.1.1 Update Verification

Start the ***Heyex*** by double clicking on the ***Heidelberg Eye Explorer*** icon located along the left side of the desktop.

Open the ***Options dialog*** by selecting the ***Setup*** menu, then selecting the ***Options*** menu item.

Select the ***Plugins*** tab of the ***Options*** window and verify that the ***FDFAcquire*** and ***FDFViewer*** modules have the version numbers indicated by the received update information.



If the versions are not listed with the correct values, please contact Heidelberg Engineering for assistance.

4 Installation Instructions for Sharing Databases between HRT and HEP

This instruction explains how to connect a new Heidelberg Engineering instrument (for example HEP) to the HEYEX database of an existing Heidelberg Engineering instrument (for example HRT).

Terminology:
Instrument A = computer of the existing instrument
Instrument B = computer of the new instrument to be added

Configuration Assumptions:

It is assumed that the newly added instrument (Instrument B) has no existing patient data and therefore no database merging will be necessary. Instead, instrument B will be pointed to the database of the existing instrument (Instrument A). Consequently, both instruments will be writing to and reading from the same database on instrument A.

Furthermore, it is assumed that the database resides on the local drive of the existing instrument A and will remain there. The two instruments are networked via a cross-over cable.

WARNING The combination of HEP and HRT must conform to the medical safety standards; in particular the leakage currents must be within respective limits specified by the international standards. To achieve this we strongly recommend using a network isolator when connecting the two systems.

Preparation

Before you start:

- Connect both instruments with an ethernet cross-over cable (X-over network cable with RJ45 connectors; 2 meters)
- Start both instrument's computers
- Remove the software protector dongle from instrument B. Ensure that the image acquisition licenses for both instruments as well as all viewing licenses have been configured for the software protector dongle on instrument A.
- Remove shortcut to Heidelberg license manager from auto start on the instrument B (start > All Programs > Startup > Right click on Helic > delete)

Step 1. Adding instruments to a workgroup

Do the following on both instruments:

Start > Control Panel > System > Tab "Computer Name" > click "Change" button > select "Workgroup" option under "Member of" > enter name of the workgroup (use same workgroup names for both instruments).

Step 2. Assigning identical username and password

The username and password for both instrument's PC need to be identical. Make sure you insert a password as Windows XP is not allowing empty passwords.

Do the following on both instruments:

Select ***Start*** › ***Control Panel*** › ***User Accounts*** › double click on ***User*** › enter ***Username*** (use the same username for both instruments) › click ***OK*** › while same user is still selected click ***Reset password*** › enter new password and confirm new password (use the same password for both instruments)

Step 3. Assigning IP Address

Do the following on both instruments:

Select ***Start*** › ***Control Panel*** › ***Network Connections*** › Right click on ***Local Area Connection*** › ***Properties*** › select ***Internet Protocol TCP/IP*** › click ***Properties*** › select ***Use the following IP address*** › Enter IP address (use different IP addresses for each instrument)

Now restart both instruments' computers

Step 4. Sharing the data and patient folder on instrument A

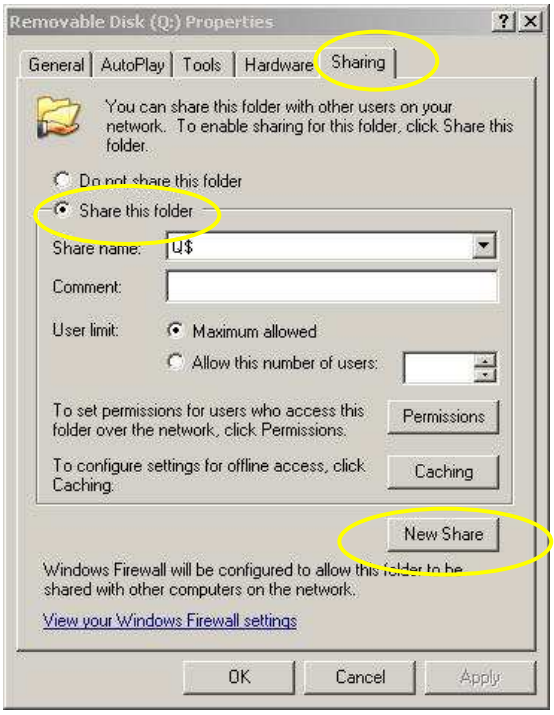
The data and patients drive on instrument A need to be shared in order to allow instrument B to access these folders.

4a) File Sharing for Windows 2003 and below

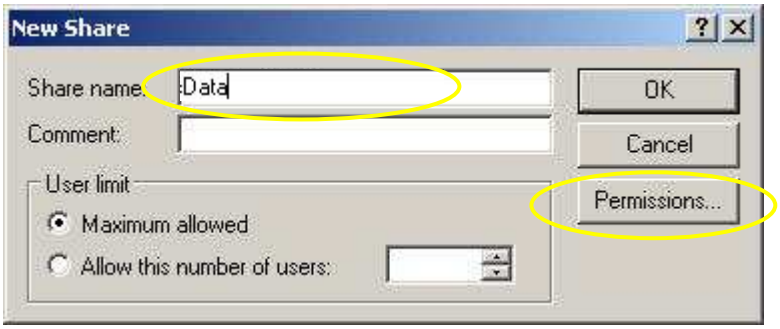
1. Double click on ***My Computer*** on Instrument A

2. Select the instrument's ***data drive***
3. Right-click on the ***Data*** folder and select ***Sharing and Security*** from the menu

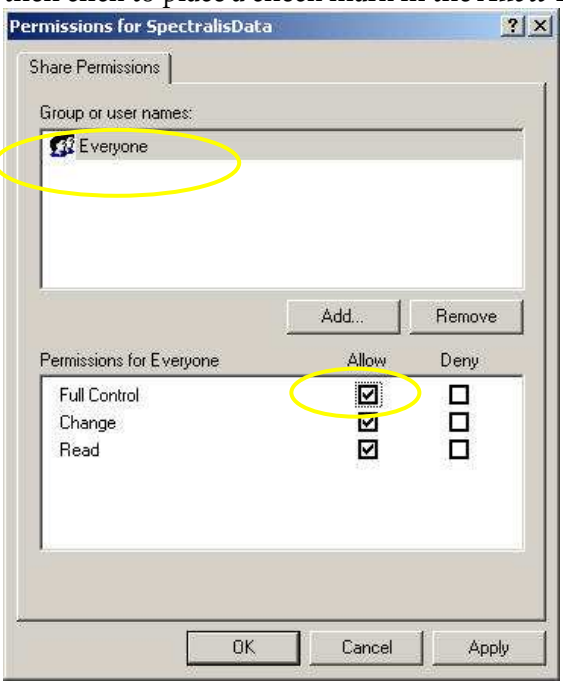
4. In the ***Properties*** window click on the ***Sharing*** tab
5. Select the radio button ***Share this folder***
6. Click on ***New Share***


Removable Disk (Q:) Properties
General
AutoPlay
Tools
Hardware
Sharing
You can share this folder with other users on your network. To enable sharing for this folder, click Share this folder.
Do not share this folder
Share this folder
Share name:
Q$
Comment:
User limit:
Maximum allowed
Allow this number of users:
To set permissions for users who access this folder over the network, click Permissions.
Permissions
To configure settings for offline access, click Caching.
Caching
New Share
Windows Firewall will be configured to allow this folder to be shared with other computers on the network.
View your Windows Firewall settings
OK
Cancel
Apply

7. In the ***New Share*** window name the share "Data"
8. Click the ***Permissions*** button



9. In the ***Permissions for*** window group or user names dialog window click once on ***Everyone*** and then click to place a check mark in the ***Allow Full Control*** box.



10. Click ***OK*** in the ***Permission for*** window
11. Click ***OK*** in the *New Share window*
12. Click ***OK*** in the *Local Disk Properties window*
13. Repeat step 1-12 for the ***Patients*** folder and enter ***Patients*** in the ***Share name*** field in step 8.

4b) Simple File Sharing (recommended with Windows XP or higher)

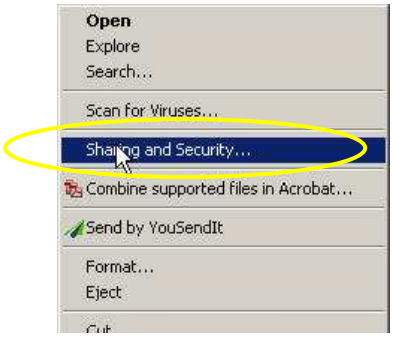
Please follow the steps listed below to properly share the data drive:

Note: If simple file sharing is not active, you have to enable it first by doing the following:

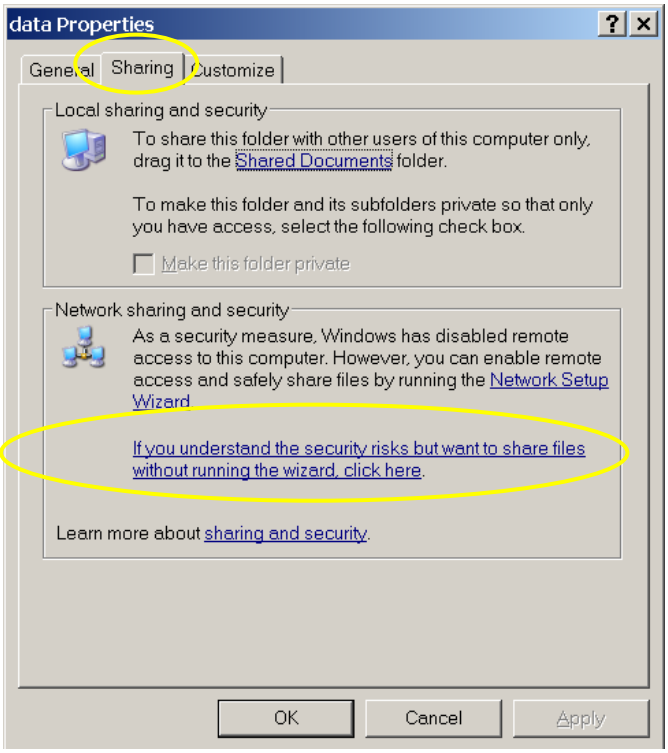
Select ***My computer – Tool menu – Folder Options – View Tab*** – select ***Use simple file sharing (recommended)*** in the list of ***Advanced Settings***

1. On instrument A, double click on ***My Computer***.

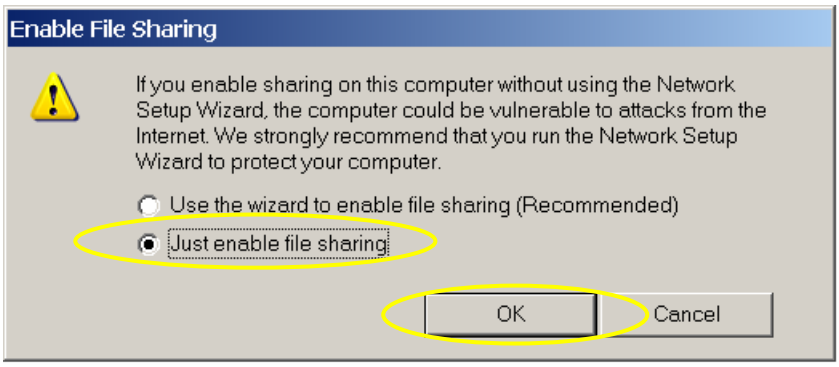
2. Select the instruments ***data drive***
3. Right click on the ***Data Folder*** and select ***Sharing and Security*** from the right click menu.



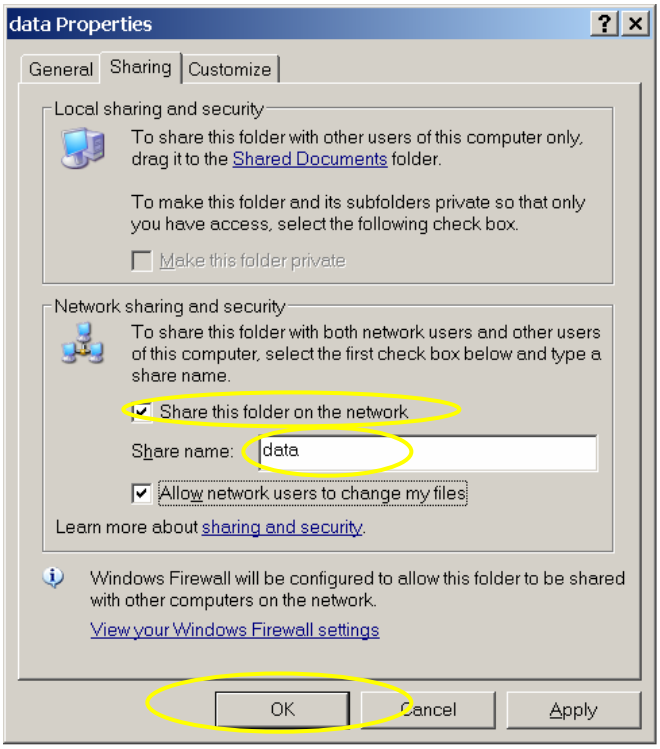
4. The ***Data Properties*** window will open. Click on the ***Sharing*** tab.
5. Click on the blue link ***If you understand the security risk but want....***


data Properties
General
Sharing
Customize
Local sharing and security
To share this folder with other users of this computer only, drag it to the Shared Documents folder.
To make this folder and its subfolders private so that only you have access, select the following check box.
Make this folder private
Network sharing and security
As a security measure, Windows has disabled remote access to this computer. However, you can enable remote access and safely share files by running the Network Setup Wizard.
If you understand the security risks but want to share files without running the wizard, click here.
Learn more about sharing and security.
OK
Cancel
Apply

6. The window ***Enable File Sharing*** will open, select ***Just enable file sharing***
7. Click ***OK***


Enable File Sharing
If you enable sharing on this computer without using the Network Setup Wizard, the computer could be vulnerable to attacks from the Internet. We strongly recommend that you run the Network Setup Wizard to protect your computer.
Use the wizard to enable file sharing (Recommended)
Just enable file sharing
OK
Cancel

8. Under ***Network sharing*** and security select ***Share this folder on the network***
9. Enter: ***"data"*** in the ***Share name*** field
10. Click ***OK***


data Properties
General
Sharing
Customize
Local sharing and security
To share this folder with other users of this computer only, drag it to the Shared Documents folder.
To make this folder and its subfolders private so that only you have access, select the following check box.
Make this folder private
Network sharing and security
To share this folder with both network users and other users of this computer, select the first check box below and type a share name.
Share this folder on the network
Share name:
data
Allow network users to change my files
Learn more about sharing and security.
Windows Firewall will be configured to allow this folder to be shared with other computers on the network.
View your Windows Firewall settings
OK
Cancel
Apply

11. Repeat step 1-10 for the ***Patients folder*** and enter "*patients*" in the ***Share name*** field in step 10.

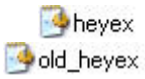
Step 5: Changing the Heyex.ini file folder paths on instrument B

1. On instrument B double click on ***My Computer***.

2. Double click on the ***C: drive***.

3. Locate the ***HEYEX folder*** and open it

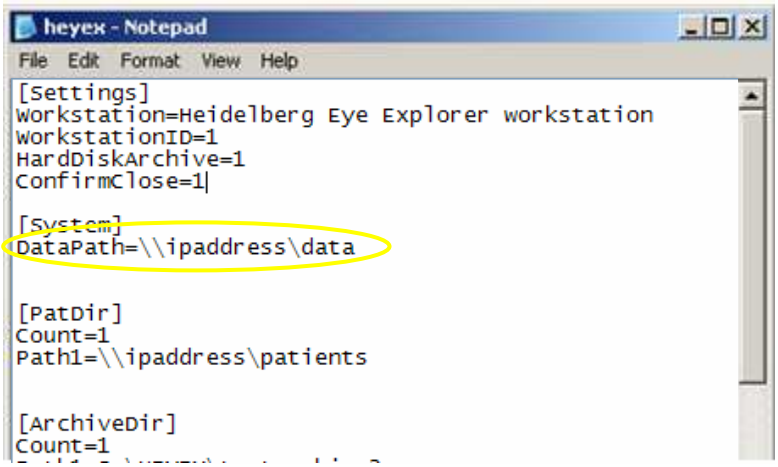
4. Select ***the heyex.ini file*** and make a safety copy (you can save it to the same HEYEX folder and rename it to "old heyex")



5. Double click on the ***heyex.ini file*** to open it

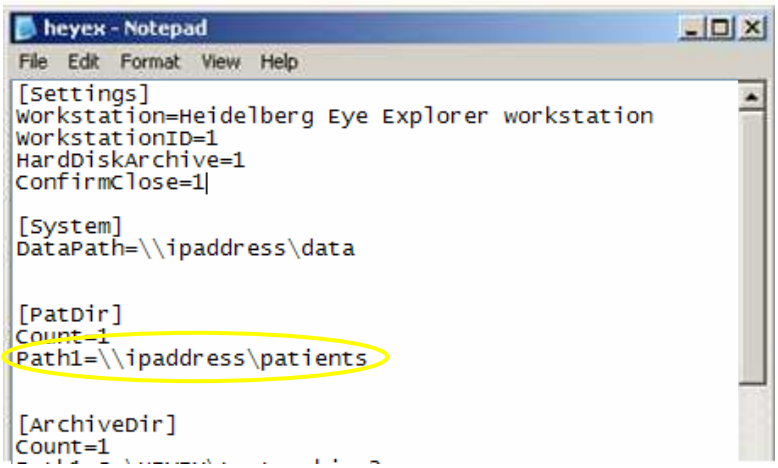
6. In the heyex.ini file, change the current ***DataPath*** to the location where the HEYEX data folder resides of instrument A.

   Example: DataPath=\\ipaddress\data



7. In the heyex.ini file, change the current *Path1* to the location where the ***patients folder*** resides on instrument A.

   Example: Path1=\\ipaddress\patients



8. Go to ***File***, then click ***Save*** to save the changes to the ini.file.

9. Open Heidelberg Eye Explorer (it may take a moment to connect to instrument A). You should now see a list of patients which was already present on instrument A.
10. Make sure you can open and modify the files.

Notes:

Remove Heidelberg license manager shortcut from ***Autostart*** on the instrument which does not host the database.

Make sure instrument A contains all software modules required for viewing and editing data acquired on instrument B.

List the software modules required for HRT and HEP:

In the case of a connection between HRT and HEP the following software modules have to be installed:

- HRT Acquisition Glaucoma Premium Edition
- HRT Viewing Module
- HEP Acquisition Module (COMP 29)
- HEP Viewing Module (COMP 30)
- Structure-Function Module (COMP 33)